

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the remarks herein, which place the application in condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 5, 14, 23, 40 and 84-110 are pending in this application.

No new matter is added.

II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Mathiowitz et al (USPN 5,985,354 hereafter "Mathiowitz") in view of Brach et al (USPN 4,720,460 hereafter "Brach"). Claims 1, 84-87 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mathiowitz in view of Unger et al (USPN 5,773,024 hereafter "Unger"). Claims 1, 88, 89, 99, 102, 103, 105, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mathiowitz in view of Yan et al (US 2003/0193102 hereafter "Yan"). The rejections are respectfully traversed.

The Examiner is respectfully directed to the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowicz*, 27 U.S.P.Q. 2d 1063 (BPAI 1992). Although a teaching, suggestion, or motivation to combine is no longer rigidly required for a finding of obviousness, it remains the primary guarantor against a non-statutory hindsight analysis. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Further, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." For the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicant's disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988).

Furthermore, The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966): "[T]he scope and content of the prior

art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

Applying the law to the instant facts, the references relied upon by the Office Action do not disclose, suggest or enable Applicants’ invention.

Applicants submit that the claimed invention has key features recited in the claims as pending, for example:

1. The biologically active ingredients may be present in the oil phase and/or the water phase and the first step involves making an water in oil emulsion. The invention relates to microencapsulation of both oil and water ingredients.
2. The water phase contains a polymerization initiator. Addition of a hydrocolloid (or the first polymer) solution to this emulsion induces a phase inversion due to polymerization of the hydrocolloid such that droplets of oil containing a water phase in them are now suspended in a continuous water phase. None of the references relied upon in the Office Action, either alone or in combination with each other, teach or suggest a phase inversion being induced by the hydrocolloid on its own. A skilled artisan at the time of the invention would have relied on emulsifiers with strong effects at the cloud point for phase inversion, namely, compounds that have more surfactant power than hydrocolloids. The novelty of the claimed invention is the use of a hydrocolloid rather than a strong surfactant to initiate a phase inversion. The use of a hydrocolloid as detailed in the present application results not only in a process effect (phase inversion) but in the final structure of the microcapsule, since the hydrocolloid will form part of the final microcapsule’s wall. There is no teaching or suggestion in any of the references cited that may lead one of skill in the art to conclude that the hydrocolloid, apart from initiating the phase inversion, is going to be essential to the final structure of the microcapsules. It is an important point of novelty of the claimed invention that the hydrocolloid has two different functions to address simultaneously.

3. Polymerization and cross-linking of the first polymer and the addition of a second polymer (the protective colloid) which also undergoes polymerization and cross-linking results in the formation of the initial basic microcapsule unit of the invention.

4. When a surfactant is added at this stage, the size of the oil droplets containing water reduces and the microcapsules are deagglomerated and then reagglomerated to result in the formation of a structure in which smaller microcapsules are enclosed within larger microcapsules. This concept is radically different from any of the mechanisms referred to in any of the references or in the art at the time of the invention.

5. The final key feature is increasing the temperature to strengthen the polymer walls of the multiple microcapsules. One of skill in the art would expect that on increasing the temperature at the end, the capsules would lose their wall structure (e.g. the temperature may be over the gelling point of some hydrocolloids), but indeed in the claimed invention this does not happen but rather there is an increase in the stability of the capsules.

The Office Action asserts that Mathiowitz at least meets the limitations of claim 1 (a-f). It is alleged that Mathiowitz discloses a continuous microencapsulation method comprising emulsifying a water phase in a oil phase where the emulsion comprises a polymerization enhancer, an emulsifier and a biological agent. The Office Action also puts forth that the result of the process described in Mathiowitz is a microcapsule with multiple coatings and a core and that the components of the core and the coatings are the same as the instant claims. Applicants respectfully submit that the reasoning of the Office Action is misguided.

The information in Mathiowitz relates to a microsphere consisting of hydrophilic polymers. It is put forth that the two polymers are dissolved in solvents to generate aqueous solutions into which the substance to be incorporated (for e.g. a biologically active ingredient) is added. This is a critical point of difference. In the claimed invention, the biologically active ingredients are incorporated into the oil and water phases while the polymers form the wall of the microcapsule, whereas in the disclosure of Mathiowitz, the biologically active ingredients are incorporated into the polymer layers itself (*See* Mathiowitz, col. 8, lines 35-51). There is no oil phase present within the microcapsules or microspheres described in Mathiowitz. Oil may be used only as a continuous phase to induce the polymers to form microspheres but is in no way incorporated in the microspheres. This is particularly evident from the Examples (*See* Mathiowitz, Example 1 and 2) in which it is stated that the oil is decanted and the microspheres

are washed with ethanol. Furthermore in selecting polymers such that the spreading coefficient of the polymer system is positive, Mathiowitz teaches that one polymer engulfs the other polymer (*See*, Mathiowitz, col. 6, lines 3-6 and col. 7, lines 52-55). Hence if one polymer forms an outer layer over the second polymer core, there is no teaching, suggestion or motivation to incorporate an oil phase within the microsphere.

Essentially, the present invention is not a microcapsule of multiple coatings as described in Mathiowitz. The final structure of the microcapsules of Mathiowitz (*See*, Mathiowitz Figures) has nothing whatsoever to do with the claimed invention. There is no teaching or suggestion in Mathiowitz that would guide a skilled artisan to arrive at different types of microcapsules in the form of multiple emulsions with some inside drops covered by a wall (the distribution of the multi-multienapsulation is an stochastic effect, and no conditions in Mathiowitz are found to result in the effect of the invention) to simultaneously protect water and oil soluble and/or dispersible ingredients.

Hence Mathiowitz does not provide any incentive or motivation to arrive at the invention of the instant claims and does not teach each and every limitation of the claims. This deficiency is not rectified by the information provided by Barach, Unger or Yan.

The Office Action alleges that Mathiowitz is silent as to the specific agents chosen in the species election and that Barach discloses a method of encapsulating bacteria in order to stabilize them. It is argued that it would be *prima facie* obvious to improve the stability of *Lactobacillus casei* using the process of Mathiowitz. It is respectfully submitted that there is no motivation whatsoever for one of ordinary skill in the art to combine the teachings of Mathiowitz and Barach. Barach relates to a method of stabilizing acid producing bacteria in a buffered solution so that the resultant compositions may be stored at temperatures above freezing for extended periods of time. As Mathiowitz describes a microsphere in which the core is a of a first polymer and the outer layer of the second polymer (*See* Mathiowitz, col. 8, lines 44-48), there would be no motivation to incorporate bacteria into a polymer core which may very well lack the space and viable environment to sustain the bacteria.

The Office Action alleges that Unger is applied to not remedy the deficiencies in method steps a-f but to address the processing limitations of claims 84-87. It is submitted that since claims 84 -87 depend on claim 1 and hence incorporate all the limitations of claim 1, Mathiowitz clearly does not disclose each and every element of claim 1 as previously elaborated and as

stated in the Office Action this deficiency is indeed not remedied by Unger. Unger relates to a container that comprises an aqueous lipid suspension and a separate gaseous phase that when agitated produces a gas-filled liposome composition that has utility as a contrast agent. The claimed invention refers to the use of inert gas to aid in the prevention of the oxidation process (for UFAs and antioxidants incorporated into the microcapsules). In no way does the disclosure of Unger, referring to the utilization of inert gas for the formation of gas filled liposomes, aid the disclosure of Mathiowitz to arrive at the oxidation retardation aspect of the claimed invention.


The Office Action alleges that Yan is applied to not remedy the deficiencies of claim 1 but to address claims 88, 89, 103, 105 and 108 which describe specific components of the oil phases and the size of the oil droplets. As stated previously, Mathiowitz does not disclose each and every element of claim 1 and this is not rectified by the disclosure of Yan. A skilled artisan would not be motivated to combine the teachings of Mathiowitz and Yan as there is no oil phase present at all in the microspheres of Mathiowitz to make the oil phase components of Yan relevant.

Hence, in view of the above arguments, none of the references, alone or in combination with each other, render the claimed invention obvious. Thus, Applicants respectfully request reconsideration and withdrawal of the pending rejections under section 103.

CONCLUSION

In view of the remarks herein, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
VEDDER PRICE P.C.
Attorney/Agent for Applicants

By: 
Michael J. Turgeon
Reg. No. 39,404
Smitha B. Uthaman, Ph.D.
Reg. No. L0613
Tel. No. (212) 407-7646
Fax No. (212) 407-7799